EPA comments on the Draft Baseline Human Health Risk Assessment Workplan
Columbia Falls Aluminum Company Superfund Site
Columbia Falls, Montana
Prepared for Columbia Falls Aluminum Company, LLC
Prepared by EHS Support LLC
Dated November 17, 2017

The comments below are intended to provide clarification on how the human health risk assessment (HHRA) will be conducted, as well as suggestions for types of information that would be helpful to include in the workplan so that consensus may be reached on critical components of the HHRA (e.g., site-specific exposure parameters).

Specific Comments

Section 1.0 (Page 1) – Please add "Superfund" when first mentioning the Site name.

Section 1.1 (Page 1) – Site Boundary –Modify this section to use the terminology "Study Area" until the extent of contamination has been determined. In Figure 1, the orange line in the legend description should also be revised to "Study Area".

Section 2.3 (Page 6) – Revise the following statement to include the potential of future land owners accessing groundwater, "*There is not current or planned use of groundwater as a potable source at the Site. In addition, based upon the depth to groundwater and current and future Site use, there is no potential for direct exposure of humans (i.e., construction workers) to groundwater at the Site*". While it may be true that water is not to be used as a potable water source at this time, this statement does not reflect potential future use if the property were to be sold in the future. Because of this, potential risk due to groundwater exposure needs to be evaluated in the HHRA.

Section 2.4.1 (Page 8) – Further evaluation is needed to support conclusions regarding cyanide presence/absence. As stated, *"Cyanide has not been detected in any of the wells during any of the ten sampling events completed by USEPA and/or CFAC since the cyanide was detected in the 2013 sampling, indicating that cyanide is not present in the groundwater beneath Aluminum City."* Cyanide has been detected in samples above the U.S. Environmental Protection Agency (USEPA) tapwater Regional Screening Level (RSL) (0.15 micrograms per liter [µg/L]) at levels of 111 µg/L and 18 µg/L. The adequacy of the detection limits for other sampling events must be evaluated relative to the tapwater RSL before conclusions can be drawn with confidence. Provide additional information on the cyanide detection limits achieved relative to screening levels with the statement referenced.

Section 2.4.1 (Page 8) – Further evaluation in the HHRA is needed to support conclusions regarding fluoride concentrations in Aluminum City and their comparability to background. Provide additional information on the fluoride concentrations observed in background samples, the number of background samples available for consideration, and a statistical comparison of the two datasets (site vs. background).

Section 2.4.2 (Page 8) – The evaluation of soil vapor is limited in that it only considers concentrations of VOCs in groundwater. Expand the soil vapor evaluation to include an assessment of soil gas data using the VISL calculator, in addition to the groundwater data. Global comment –

modify all statements that occur later in the document to include information on soil gas and groundwater.

Section 2.4.3 (Page 9) – Expand the conclusion that "*there is no potential for exposure to asbestos by human receptor activity in the Asbestos Landfills*" to state under what conditions this is true. Because only surficial soils were sampled, characterization of subsurface soils is lacking. If subsurface soils are disturbed, there is potential for asbestos exposure. In addition, it needs to be noted that asbestos-containing building material have a tendency to rise from the subsurface and become exposed.

Section 2.4.2 (Page 9). Please include a citation for the toxicity equivalency factors that were used in the evaluation. Please expand this evaluation to include a table of the comparisons to RSLs. This applies to all three bullets where conclusions are drawn based on a comparison that is not presented.

Section 2.5 (Page 10) – It is inappropriate to consider mitigation factors at this stage in the CERCLA process. In accordance with USEPA risk assessment guidance for Superfund (USEPA 1989), the baseline HHRA "*...is an analysis of the potential adverse health effects (current or future) caused by hazardous substance releases from a site in the absence of any actions to control or mitigate these releases (i.e., under an assumption of no action).*" The risk assessment should present risks to receptors at the Site under current and future conditions if no actions were taken to limit potential exposures; it is not appropriate to evaluate future conditions if mitigation were to occur. Please remove mention and application of mitigation factors.

Section 2.5 (Page 10) – The workplan would benefit from having a figure/flow diagram depicting the conceptual site model.

2.5.2 (Page 11) – The workplan does not address how will ingestion of game will be evaluated at the Site. Because animals will not restrict their use to certain exposure units where recreational receptors may hunt, consideration of the mobility of game animals is needed. Granted there may not be designated recreational use in an exposure unit, the game animals will be exposed to multiple exposure units (EUs) (i.e., those that are accessible to animals). Text describing the approach for evaluating game tissue ingestion needs to be added.

2.5.3.11 (Page 18) – The HHRA should evaluate exposures due to groundwater ingestion for the most conservative receptor in each EU at a minimum under a hypothetical future use scenario to demonstrate if groundwater could be used for consumption in the future.

3.1.1.1 (Page 20) – Provide clarification regarding the use of samples collected using discrete and incremental sampling methodology (ISM). The workplan must explain how exposure point concentrations (EPCs) will be calculated in each of the EUs given the differences in sample collection techniques.

3.1.1.2 (Page 20) – The workplan must provide a discussion of data quality, beyond completeness and rejected data. This discussion should include information on sample representativeness, method comparability, result accuracy and precision, sample variability, and analytic sensitivity.

3.1.1 (Page 20) – Please add a discussion of the representativeness of the data for each EU and media type. This discussion must determine if available data are representative of the range of temporal and spatial variability at the Site and whether every EU have been adequately characterized. In particular, in cases where only discrete soil samples are available for an EU or when only one ISM replicate is available for an EU, the workplan must discuss whether the available data are adequate to support a risk characterization of soil.

Section 3.1.1.3 (Page 21) – Please provide a citation for the USEPA RSL version that was used in the chemical of potential concern (COPC) selection.

Section 3.1.1.3 (Page 21) – Please provide an explanation for how COPCs will be selected for media types other than soil, sediment, and surface water (e.g., game tissue, fish tissue, and air).

Section 3.1.1.3 (Page 22) – Revise the last bullet. Granted that "*groundwater data indicate[ing] that leaching of the COPC in the soil is not affecting the groundwater quality*", it must be demonstrated in the risk assessment rather than cited in another source.

Section 3.1.1.3 (Page 22) – Revise the workplan to clearly discuss how background data will be used in the risk assessment process. In accordance with USEPA guidance (USEPA 2002a), background data may be used in the risk characterization to determine if risks are attributable to the Site, but chemicals should not be removed during the COPC selection process on the basis of background.

Section 3.1.1.3 (Page 22) – Revise the workplan to identify the basis of toxicity values, in cases where the selected values are not directly used as presented in the USEPA RSL table. See below for example text that should be included for chromium for additional information:

> Chromium: Although measured chromium concentrations in environmental media were based on total chromium, for the purposes of COPC selection, maximum concentrations will be compared to RSLs based on hexavalent chromium [Cr(VI)], which is the more toxic form. The RSL table identifies screening levels for oral exposure to soil or water based on the assumption that Cr(VI) is carcinogenic by the oral route. However, EPA's Integrated Risk Information System (IRIS) database states "No data were located in the available literature that suggested that Cr(VI) is carcinogenic by the oral route of exposure." For this reason, the screening levels for Cr(VI) in soil and water will be set equal to the non-cancer RSLs.

Section 3.1.1.3.1 (Page 22) – It is recommended the workplan consider the future changes to the lead criterion. The November 2017 version of the USEPA RSL table presents a value of 400 milligrams per kilogram (mg/kg) as the residential lead soil screening value, however, this value is based on a target blood lead level of 10 micrograms per deciliter (µg/dL) and does not reflect recent changes in USEPA guidance on lead modeling (e.g., USEPA 2017a,b). USEPA Region 8 recommends the following when performing lead risk assessments: evaluate risks for a range of target blood lead levels (i.e., 5, 8, and 10 µg/dL), employ modified ingestion rates (von Lindern et al. 2016), revise the child age range to be 12-72 months (USEPA 2017b), revise the maternal blood lead to 0.8 µg/dL (USEPA 2017a), and change the default water concentration to 0.8 µg/L. It is recognized that the current version of the USEPA RSLs (November 2017) do not reflect these changes. However, these changes in approach were recently approved by the USEPA Technical Review Workgroup (TRW) during the lead consultation for another Region 8 Superfund site (Eagle Mine). Evaluation of risks due to lead will be revisited at the time of the 5-year review for the Site;

however, inclusion of these changes now may limit potential future re-work as part of the 5-year review. This is a global comment to be considered for all receptors.

Section 3.1.1.3.1 (Page 23) – Discussion of the comparison of Site and background concentrations is not appropriate in this document. All discussion of background should be removed from this document. This is a global comment.

Section 3.1.1.4 (Page 35-36) - The data gaps analysis presented is lacking in detail. Please add a discussion of the temporal variability. Because data were collected during one calendar year, additional discussion/evaluation is needed on how these data compare with other years when climatic conditions, groundwater movement, and surface water flow conditions are different. Expand the discussion regarding sample density to include an evaluation of the variability of the data within each EU. If data are highly variable and sample density is low, this would also indicate that additional sampling may be warranted. It should be noted that any future data collected must be considered in the COPC selection. The discussion of surface water and sediment data concluded the sampling density is moderate. However, given that only one year of sampling has been conducted, the temporal representativeness of the data would be improved with additional data collection. There is no discussion of game or fish tissue that may be ingested by recreational receptors who may hunt or fish or that data for these exposure media are lacking. The workplan must discuss the limitations of estimating game/fish tissue concentrations.

Section 3.1.1.4 (Page 36) - As noted above, chemicals should not be removed during the COPC selection process on the basis of background (USEPA 2002b). Remove any statements that discuss removal of chemicals from the list of COPCs due to background.

Section 3.1.2.1 (Page 36) –There appears to be confusion regarding variability and uncertainty. In risk assessment, the central tendency exposure (CTE) and reasonable maximum exposure (RME) are intended to represent the range of *variability* within the population of interest, whereas use of the 95% upper confidence limit (95UCL) on the mean is intended to address *uncertainty* in the exposure point concentration (EPC). RME exposure parameters represent reasonable maximums, such that exposure parameters are adequately conservative for high-end exposures. However, uncertainty in the mean applies to both the CTE and RME scenarios (USEPA 1992; 2001); per USEPA guidance, the 95UCL should be employed as the EPC for both (see Section 1.2.4 of USEPA [2001] for an explicit statement in this regard). Please revise this discussion as appropriate.

Clarification is also needed in discussion of the "UCL". USEPA recommends that the 95UCL of the arithmetic mean for each exposure area be used as the EPC when calculating exposure and risk at that location (USEPA 1992).

The maximum concentration should not be selected as the EPC when the 95UCL exceeds the maximum concentration. The approach outlined in the workplan is inconsistent with USEPA's *ProUCL Technical Guide* (Version 5.1; USEPA 2015).

Section 3.1.2.2 (Page 37) – Currently, the workplan only includes blank example table templates for the exposure parameters. Revise the workplan to include the actual exposure parameters that are intended for use in the HHRA. This is necessary so that consensus can be reached on selected values when they are based on professional judgement or are considered to be Site-specific.

Section 3.1.2.2 (Page 37) – Please include the following in the list of guidance documents:

- Human Health Evaluation Manual, Supplemental Guidance: Update of Standard Default Exposure Parameters. OSWER Directive 9200.1-120 (EPA 2014)
- Risk Assessment Guidance for Superfund, Volume I, Human Health Evaluation Manual (Part A) (EPA 1989)
- Supplemental Guidance for Developing Soil Screening Levels for Superfund Sites (EPA 2002b)
- Standard Default Exposure Factors. OSWER Directive 9285.6-03 (EPA 1991)

Section 3.1.2.2 (Page 37) – It is unclear how the concentrations in air will be estimated for use in risk calculations. Please provide text describing the proposed approach; include specifics on the equation and inputs/assumptions that will be used to calculate the particulate emission factors (PEFs).

Section 3.1.2.2 (Page 37) – Rather than reference the "*USEPA RSL exposure equations*", please include the dose-based equations that will be used to calculate daily intake rates for the various exposure routes that are complete at the Site.

Section 3.1.2.2 (Page 37) – Please include information regarding the age range for receptors at the Site and the approach for time-weighting the exposure of receptors based on their lifetime exposure risks, as recommended in USEPA guidance (USEPA 1989).

Section 3.1.3 (Page 38) – Please include information on the sub-chronic exposure scenarios, if any, that will be evaluated and provide an explanation for how this evaluation will differ from the chronic exposure evaluation.

Section 3.1.3 (Page 38) – For metals with different toxicity values for different chemical forms, the toxicity values selected should be based on the chemical form most similar to that expected to occur at the Site. Points to note regarding chemical form are listed below for consideration.

- Two oral RfD values are available for cadmium, depending on exposure medium (food or water). The value for water is assumed to apply to surface water and groundwater, while the value for food is assumed to apply to all other media (i.e., soil, sediment, fish and game tissue, and air).
- Two oral RfD values are available for manganese depending on exposure medium (diet or non-diet). The value for diet is assumed to apply to items in the diet (i.e., fish and game tissue), while the value for non-diet is assumed to apply to all other media types (i.e., soil, sediment, air, and water). The non-diet RfD for manganese (4.7E-02 mg/kg-day) is based on the oral RfD of 1.4E-01 mg/kg-day in the diet. In accordance with recommendations in IRIS, for application to non-diet exposures, the RfD should be adjusted by dividing by a modifying factor of 3.

- The RSL table identifies an oral slope factor for Cr(VI). However, IRIS states "No data were located in the available literature that suggested that Cr(VI) is carcinogenic by the oral route of exposure." For this reason, Cr(VI) should not be evaluated as an oral carcinogen.

- Chromium exists in the environment mainly as Cr(III) (ATSDR 2000). However, because the valence state of chromium in soil or water at this Site is not known and data are available only for total chromium, risk calculations should assume the ratio of Cr(III) to Cr(VI) is 6:1 (EPA 2013).

Section 3.1.4 (Page 40) – Please provide a table summarizing target organ for each COPC that will be used in the HHRA when evaluating non-cancer hazards.

Section 3.1.4.1 (Page 40) – Please provide a list of the uncertainties that will be discussed in the HHRA. The following uncertainties are expected to be discussed at a minimum:

- Uncertainties in Exposure Assessment:
    - Uncertainties from exposure pathways not evaluated
    - Uncertainties from chemicals not evaluated
    - Uncertainties in exposure point concentrations
    - Uncertainties in data adequacy (spatial and temporal representativeness of each media type)
    - Uncertainties in non-detect results - detection limit adequacy
    - Uncertainties in human exposure parameters
    - Uncertainties is dietary tissue estimation
- Uncertainties in Toxicity Values
- Uncertainties in Risk Estimates

General Comments:

A formal background evaluation is required to substantiate any conclusions drawn regarding risks from chemicals not being Site-related. Ideally, this would be presented using multiple lines of evidence (statistical comparison of regional background data to Site data, statistical comparison of Site-specific background data to Site data, graphical presentations, and evaluation of risks based on background concentrations).

References

USEPA 1989. Risk Assessment Guidance for Superfund, Volume I, Human Health Evaluation Manual (Part A). Office of Emergency and Remedial Response, Washington, D.C. EPA/540/1-89/002. December.

USEPA 1991. Standard Default Exposure Factors. OSWER Directive 9285.6-03.

USEPA. 1992. U.S. Environmental Protection Agency, Office of Solid Waste and Emergency Response. Supplemental Guidance to RAGS: Calculating the Concentration Term. Publication 9285.7-081.

EPA. 2001. *Risk Assessment Guidance for Superfund: Volume III, Part A, Process for Conducting Probabilistic Risk Assessment.* U.S. Environmental Protection Agency, Office of Emergency and Remedial Response. EPA 540-R-02-002. December 2001.

EPA. 2002a. Guidance for Comparing Background and Chemical Concentrations in Soil for CERCLA Sites. U.S. Environmental Protection Agency, Office of Emergency and Remedial Response. EPA 540-R-01-003. September. <http://www.epa.gov/oswer/riskassessment/pdf/background.pdf>

USEPA 2002b. Supplemental Guidance for Developing Soil Screening Levels for Superfund Sites. OSWER 9355.4-24.

USEPA 2014. OSWER Directive 9200.1-120. Human Health Evaluation Manual, Supplemental Guidance: Update of Standard Default Exposure Parameters.

USEPA. 2015. ProUCL Version 5.1.00 Technical Guide. U.S. Environmental Protection Agency, Office of Research and Development. EPA/600/R-07/041. October 2015. https://www.epa.gov/sites/production/files/2016-05/documents/proucl_5.1_user-guide.pdf.

USEPA. 2017a. OLEM Directive 9285.6-56 "Update to the Adult Lead Methodology's Default Baseline Blood Lead Concentration and Geometric Standard Deviation Parameters". May.

USEPA. 2017b. OLEM Directive 9200.2-177 "Recommendations for Default Age Range in the lEUBK Model". November.

von Lindern, I., M. Stifelman, L. Stanek, AND C. Bartrem. 2016. Estimating Children's Soil/Dust Ingestion Rates through Retrospective Analyses of Blood Lead Biomonitoring from the Bunker Hill Superfund Site in Idaho. ENVIRONMENTAL HEALTH PERSPECTIVES. National Institute of Environmental Health Sciences (NIEHS), Research Triangle Park, NC, 124:1462–1470.